

6. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	ReFlow Medical
TRADE NAME:	Wingman Extendable Tip Support Catheter
COMMON NAME:	Guide Catheter
CLASSIFICATION NAME:	Percutaneous Catheter
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 870.1250
PRODUCT CODE	DQY
AUG 11 2010	
PREDICATE DEVICES: Outback Catheter (K001577) QuickCross Support Catheter (K 072750) Gopher Support Catheter (K091345)	

Substantially Equivalent To:

The Wingman Extendable Tip Support Catheter is substantially equivalent in intended use, principal of operation and technological characteristics to the Outback Catheter, the QuickCross Support Catheter and the Gopher Support Catheter.

Description of the Device Subject to Premarket Notification:

The Wingman Extendable Tip Support Catheter is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The device consists of a support catheter, with a concealed radiopaque beveled guide-tip, and activating handle. The through-lumen of the device can serve as a conduit for the delivery of diagnostic and therapeutic agents.

Indication for Use:

The Wingman Extendable Tip Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

Technical Characteristics:

The Wingman Extendable Tip Support Catheter has similar physical and technical characteristics to the predicate devices.

Performance Data:

All necessary verification and validation testing has been performed for the Wingman Extendable Tip Support Catheter to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Comparative simulated use testing demonstrated that the Wingman Extendable Tip Support Catheter is substantially equivalent to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Wingman Extendable Tip Support Catheter is determined by ReFlow Medical, to be substantially equivalent to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Reflow Medical
c/o Ms. Rebecca K. Pine
Head of Regulatory Affairs/Quality Assurance
5311 Foxhound Way
San Diego, CA 92130

AUG 11 2010

Re: K101479

Trade Name: Wingman Extendable Support Catheter
Regulation Number: 21 CFR§ 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 15, 2010
Received: July 16, 2010

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

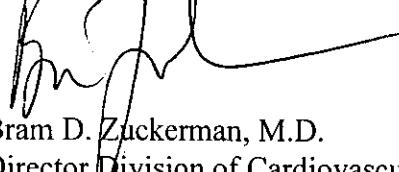
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director Division of Cardiovascular
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

K101479

INDICATIONS FOR USE STATEMENT

AUG 11 2010

510(k) Number (if known): _____

Device Name: **Wingman Extendable Tip Support Catheter****Indications for Use:**

The Wingman Extendable Tip Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

AND/OR

Prescription Use X
(Part 21 CFR 801 Subpart D)Over-The-Counter Use _____
(21 CFR 801 Subpart C)**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)****Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101479

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